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Performance verification of portable Celercare M1 analyzer in CRP determination

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【Abstract】 Objective: To verify the analytical performance of the portable Celercare M1 analyzer in the C-reactive protein (CRP) quantitative determination.

Methods: According to the standard program of the American Clinical and Laboratory Standards Institute (CLSI), The portable Celercare M1 analyzer was performed the verification on the CRP detection in the aspects of the linearity range, precision, accuracy, interference test and method comparison.

Results: The CRP detection showed good linearity in the range of 0.5-200 mg/L and the regression equation was $Y=0.979X+0.456$. The within-run coefficients of variation (CV) of samples with low and high CRP levels were 5.9% and 2.0%, respectively. The between-day CV of samples with low and high CRP levels were 6.3% and 2.2%, respectively. The accuracy of the assay was admirable, and bias of CRP results at low and high levels were 2.3% and 0.7%, respectively. No significance interference was observed when serum bilirubin ≤ 340 $\mu\text{mol/L}$, triglyceride ≤ 10 mmol/L and hemoglobin ≤ 8 g/L in this method, The regression equation of Celercare M1 analyzer (Y) and the IMMAGE 800 (X) for detecting CRP was $Y=0.944X+0.206$, $R^2=0.996$ ($P<0.001$). The relative bias of CRP results in three medical decision levels (3.0 mg/L, 10.0mg/L, 100.0 mg/L) was 1.0%, 4.0% and 5.0%, respectively, which was lower than 1/2 of total error allowance.

Conclusions: The linearity, precision, accuracy and interference of the Celercare M1 analyzer in CRP determination are admirable and can be accepted in clinical practice.

【Key words】 C-reactive protein; performance evaluation; Celercare M1 analyzer